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NATIONAL
FOOD
PROCESSORS
ASSOCIATION

January 24, 2005

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: [Docket No. 2004G—0381] Draft Guidance for Records Access Authority Provided In Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability (69 *Federal Register* 71657; Dec. 9, 2004)

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits these comments on the draft guidance for records access authority provided in the Bioterrorism Preparedness and Response Act of 2002 (hereinafter the "Act").

The National Food Processors Association is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. In 2005, NFPA will become the Food Products Association (FPA).

NFPA commends FDA for developing guidance to assist the industry in implementing the final records rules recently published in 69 *Federal Register* 71562 (Dec. 9, 2004). We encourage FDA to consider our comments in refining this guidance to clarify the proposed actions and intent of FDA so that industry may more easily and effective comply with the records provisions of the Act.

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Specific Comments for FDA:

Prevention of "warrentless" government request for records

Under the provisions of the Act, the records FDA is authorized to require by regulation are confined to those necessary "to address credible threats of serious adverse health consequences or death to humans or animals." Neither the regulation nor the Draft Guidance codify any concrete, enforceable procedural safeguards to ensure that such records searches conform with the law as a matter of fact. Further, while the Fourth Amendment limits FDA's authority to conduct searches to those that are "reasonable," the Rule and Draft Guidance provide no safeguards to ensure that the expanded authorities provided under the Bioterrorism Act are implemented in accordance with these constitutional limits on agency authority. It is our understanding that FDA has indicated determination of serious adverse health consequences or death conditions will be determined by FDA on a case-by-case basis. Industry would prefer more definition into what constitutes a treat and what safeguards FDA will use to ensure records searches will conform to legal standards. Absence of procedural safeguards to confine warrantless government search of private business records is of concern to the food industry. The Draft Guidance does not reflect a considered approach to the issues involved with respect to limits on agency authority. Without a concrete and transparent resolution to these issues in advance of a triggering "emergency," procedural safeguards will be considered only on an ad hoc basis and in the compromising atmosphere typical of perceived "crises." Industry strongly suggests the need for well defined procedures and evidentiary standards that reflect the boundaries of government discretion.

Recordkeeping requirements applied to intrastate food-related activities

FDA's application of the requirements of the Final Rule to intrastate activities raises an important Constitutional law issue. It appears FDA interprets the Bioterrorism Act to impose no limitation on extending recordkeeping requirements to persons engaged solely in intrastate commerce. The agency argues that, given the collective impact on commerce of intrastate manufacturing, processing, packing, transporting, distributing, receiving, or holding food in the United States, the requirements in the Final Rule should apply regardless of whether the food enters interstate commerce. FDA asserts further that it is appropriate for purely intrastate activities to be subjected to these federal controls because a significant food-related emergency would have the same effect on the public health regardless of whether the food had originated from an out-of-state source. We remind FDA that FDA's jurisdiction over intrastate commerce is confined to matters affecting interstate commerce as defined under the applicable standards of the Commerce Clause of the U.S. Constitution. We also remind FDA that presumption of enforcement under section 709 would be overcome in particular cases in which it could be established that the agency action had overstepped this constitutionally imposed boundary.

Protection of trade secrets and other confidential information

Section 414 (c) of the FDCA, as amended by the Bioterrorism Act, requires the Secretary to "take appropriate measures to ensure that there are in place effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary" pursuant to the Section 414 recordkeeping requirements. However, neither the Final Rule nor the Draft Guidance provide express procedures or standards to ensure that the property rights and privacy interests of covered persons are respected and protected, or that would enable companies whose rights are at risk of infringement to enforce their rights within the ordinary course of business. FDA states that it plans to reemphasize to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained. With respect to recipes for food, FDA argues that the agency may require information about contaminated spices, flavorings and certain colors that may be used in proprietary formulas in order to effectuate the public health purposes of the Act. In some cases, this proprietary formula information is a trade secret and confidential in nature. We believe FDA must engage its personnel in confidential material awareness training in a structured manner with regard to the confidentiality issue and that more than just a reminder to personnel is warranted. FDA should provide training for its staff and also inform the public of the procedural safeguards in place to obtain the information needed without jeopardizing confidential business information.

Official records request and threat information

We interpret the proposed regulation to indicate that the authorized FDA representative would present any and all records requests in a written format. It will be helpful in an investigation for FDA to tell the company about the nature of the threat as well as what records the FDA wishes to inspect. The written document should include a summary of the threat basis so that companies can begin to conduct parallel investigations and take actions accordingly.

We remind FDA that as part of the facility registration component of the Bioterrorism Preparedness and Response Act, facility emergency contact information is required. FDA has indicated use this information in case of an emergency to notify the facility of the nature of the emergency and that a company person or entity should be available 24 hours a day, 7 days a week. We believe this emergency contact information, already on file with FDA, is an excellent means to alert a company of a forthcoming request for records related to a determination of serious adverse health consequences or death conditions.

Also, the specific site of investigation may not be the company headquarters. NFPA members suggest that the written request also be transmitted to the company headquarters, in addition to that presented at a facility, so that an overall company response can be as timely and efficient as possible.

Evaluation of the effectiveness of a company's recordkeeping and records access programs

It is our understanding that routine FDA inspections will not include an assessment of a company's programs and systems to comply with these recordkeeping rules. The ability of a company to comply will be determined during an actual event where FDA makes a formal records request due to reasonable belief of a threat. To date, industry has already experienced FDA inspectors requesting recordkeeping information. Since this is not authorized by the Act nor intended as part of the final rule, industry would suggest FDA develop internal guidance for its inspectors to clarify their role and that their requests for records under the rule during routine inspections are inappropriate.

Thank you for the opportunity to comment on this guidance document. If you should have questions or need clarification on any of the above, please contact us.

Sincerely,

Jeffrey T. Barach, Ph.D.
Food Products Association (formally National Food Processors Association)